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10/036,487	01/07/2002	Spiros Fotinos	224.0509-US	3570

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EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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10/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/036,487

**Applicant(s)**

FOTINOS ET AL.

**Examiner**

Blessing M. Fubara

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 46-50 and 55-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-50 and 55-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks 08/03/07. Claims 46-50 and 64 are amended. Claims 51-54 are canceled. New claim 70 is added. Thus, claims 46-50 and 55-70 are pending.

Although, applicant indicates in the remarks, under the heading "amendments to the claims," it is noted that claim 57 is not amended.

**Previous rejections that are not reiterated herein are withdrawn.**

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 48 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

The original specification as filed does not support a range of 78 to 86% wt% for polyvinylpyrrolidone in amended claim 48. The original specification does not provide support for a range of 0.9 to 5.5 wt% for polyethylene glycol in amended claim 50.

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Thus, the original specification does not envision 78 to 86% wt% for polyvinylpyrrolidone as is now recited in amended claim 48 and the original specification does not also envision 0.9 to 5.5 wt% for polyethylene glycol as is now recited in amended claim 50.

However, it is noted that the Tables 1 and 2 support specific percent amounts for the polyvinylpyrrolidone and polyethylene glycol and not ranges. For the above ranges to be valid, all points within the range should have been disclosed or the claimed ranges should have been describe. In this case none of this has happened, rather specific points have been described.

### ***Response to Arguments***

3. Applicant's arguments filed 08/03/07 have been fully considered but they are not persuasive.

With respect to polyvinylpyrrolidone and polyethylene glycol present in the delivery device of claim 46 in amount of from 78-86 wt% by dry weight (recited in amended claim 48) and 0.9 to 5.5 wt% (recited in amended claim 50) respectively, applicant argues that the decision in *in re Wertheim* 541 F.2d, 257, 191 USPQ 90 (CCPA 1976) supports the recitation of the claimed range of from 78 to 86 wt% and 0.9 to 5.5 wt% and one skilled in the art would consider the ranges in claims 48 and 50 to be inherently supported by that provided in the Examples.

### **Response:**

The ranges in claims 48 and 50 are not inherently disclosed by the Examples because specific percent points are named in the Examples and the specification does not disclose or envision the ranges in claims 48 and 50. The applicant points out that in *in re Wertheim*, a disclosed range of "25% -60%" was found to support limitation of "between 35% and 60%"

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claimed. However, in the presently examined case, there is no disclosure of a range that encloses or encompasses the claimed ranges and just as applicant admits that specific Examples of “36%” and “50%” does not meet the description requirements of “at least 35%” in the *in re Wertheim* decision, the specific percentage points in the Examples in Tables 1 and 2 does not provide written description for the ranges in claims 48 and 50. Therefore, *in re Wertheim* supports the position that the skilled artisan would not consider the ranges in claims 48 and 50 to be inherently supported by the specific points provided by the Examples.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 46, 50, 56 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Belsole (US 4,696,821).

Belsole discloses transdermal delivery system comprising nitroglycerin, polyvinylpyrrolidone, polyethylene glycol (abstract; column 2, line 9 to column 3 and line 22; Examples 1-4) and solvent (column 2, line 16). The nitroglycerine meets cardiovascular agent of claim 59 and therapeutic agent of claim 56. The polyvinylpyrrolidone polymer film (column 2, line 36) is single layer and the composition within the polymer film is inherently homogenous meeting the requirements of amended claim 46. The dry weight of nitroglycerin is 0.091 X 26.37 = ~2.40 gram making the % polyethylene glycol based on dry weight to be  $1/(26.37 + 2.40)$

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+ 1 + 5) X 100 = 2.87 for Example 1, which touches a point within the recited range of 0.9 to 5.5 wt% for the polyethylene glycol in claim 50. A uniform layer that dissolves onto a wetted skin tissue or mucosal epithelial tissue when applied to the skin according to claim 46 is a property of the device/composition such that the device of Belsole inherently has that property.

6. Claims 46, 55-60, 62, 64 and 66-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Biederman et al. (US 5,980,921).

Biederman discloses a toilet bar that contains active agent such as Niacinamide, pyridoxine, panthenol, pantothenic and mixtures thereof as the primary actives at amounts of 0.1% to about 10% (column 4, lines 21-28), surfactant such as lauryl sulfate, polyvinylpyrrolidone, polyethylene glycol plasticizer in amounts of 0.5% to 30% (column 2, lines 42-46; column 3, lines 19-21; column 4, lines 38-43; column 5, lines 4-16; column 6, lines 17-28 and 39-46; column 9, lines 37,43; column 10, lines 12-38) and other active agents namely: anti-inflammatory agents, retinoids, antimicrobial agents, antiandrogens, sunscreens, sunblocks, anti-oxidants/radical scavengers, chelators, hydroxyl acid anti acne agents such as salicylic acid and lactic acid, desquamation agents, depilation agents and skin lightening agents (columns 11-16). Specifically the composition is non tacky because the preferred polymer, which is polyvinylpyrrolidone and the plasticizer are chosen to reduce tacky sensation on users hands during application (column 10, lines 39-46). The polyvinylpyrrolidone meets the requirement for filmogenic polymer of claim 46. The other active agents (columns 11-16) meet the requirements of claims 56-59. Lauryl sulfate meets the requirements of claim 55. The 0.1% to about 10% for the active agent touches points within the recited range of 0.1% to 15% in claim 64. The use of the toilet bar on the skin tissue involves wetting of the skin, application of the

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toilet bar and rinsing off of the foam from the skin meets claims 66-69. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 46, 49, 50 and 55-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biederman et al. (US 5,980,921).

Claims 49 and 50 are included in this rejection in view of the amendment to the claims.

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Biederman discloses topical composition comprising effective amount of active agent in a more preferred amount of about 0.1% to about 10% and cosmetically acceptable topical carrier such as propylene glycol and polyethylene glycol (column 2, lines 42-46; column 3, lines 19-21; column 4, lines 38-43; column 5, lines 4-16). The composition of Biederman is formulated as a cleansing composition in the form of bath gels, liquid, shampoos, hair tonic, pastes and mousses; the composition comprises surfactants such as sodium lauryl sulfate in a preferred amount of from about 5% to about 10% (column 6, lines 17-28 and 39-46); the composition comprises film forming polymer that is not tacky (column 8, lines 56-67). Polyvinylpyrrolidone, one of the preferred polymers is present in amounts of 0.5 wt% to 10 wt% (column 9, lines 37, 43); wherein the composition further comprises plasticizers such as glycols and glycerol in amounts of about 0.5% to 30% (column 10, lines 12-38). It is specifically disclosed that the preferred polymer and the plasticizing solvent (plasticizer) are chosen such that the polymer and the plasticizing solvent are in the aqueous phase of the emulsion which reduces tacky sensation of the polymer on the users hands during application (column 10, lines 39-46). Niacinamide, pyridoxine, panthenol, pantothenic and mixtures thereof are the primary actives (column 4, lines 21-28). In addition to the primary actives, the composition of Biederman optionally contains other active agents namely: anti-inflammatory agents, retinoids, antimicrobial agents, antiandrogens, sunscreens, sunblocks, anti-oxidants/radical scavengers, chelators, hydroxyl acid anti acne agents such as salicylic acid and lactic acid, desquamation agents, depilation agents and skin lightening agents (columns 11-16). Polyvinylpyrrolidone meets the limitation of claims 46. Antimicrobials meet the limitations of claims 56-59. Lauryl sulfate meets the limitation of claim 55. Propylene glycol and lauryl sulfate meet the limitation of permeation enhancer. As a



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cleansing product, the composition of Biederman meets the claims 46 and 55-69. The comprising language of the claims is open and does not exclude other components present in the composition of Biederman.

Biederman is discussed above and discloses the film forming composition of the claimed invention. Biederman does not disclose a single layer device. Regarding the percent amounts of the components, there is no demonstration that these amounts in combination provides unexpected results to the compositions when a range is claimed indicating variable amounts that can be optimized for the desired use. The cleansing formulation is applied to the skin and the application may be in a single layer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the composition of Biederman to the skin as a cleansing composition. One having ordinary skill in the art would have been motivated to apply the composition to the skin in a single layer with the expectation of uniform/efficient cleaning.

#### ***Response to Arguments***

10. Applicant's arguments filed 08/03/07 have been fully considered but they are not persuasive.

Applicant argues that the examiner recognizes in the office action of 4/10/2007 that Biederman does not disclose a single layer device and that claim 46 requires a single layer device; that "nowhere does not the record show any reference that teaches or suggests a thin film composition or device according to claim 46 for use in commerce;" that "claim 46 describes a device that dissolves on wetted skin and that is film before such application, thus clearly

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distinguishing a film that a may form on the skin of one using any other type of device” that Biederman does not recognize a need for a cleansing composition in the form of a thin film and does not teach or suggest types of materials for preparing such a thin film; that “claim 46 describes something never before taught or suggested by the art of record;” that the recitation of “consisting essentially of” clearly distinguishes the claimed film over the “hypothetical film on the surface of” Biederman’s toilet bar.

**Response:**

As an initial matter, it is noted that the amended claim 46 broadly describes a composition that consists essentially of a single uniform film layer that is not tacky and comprises polyvinylpyrrolidone and polyethylene glycol. In this respect, the composition/toilet bar of Biederman comprises polyvinylpyrrolidone and polyethylene glycol as described in the rejections and as admitted by applicant in the remarks that the composition within the film layer is described with the term “comprising” so that the composition of Biederman is open to all the ingredients contained in the composition. The rejection is not one of anticipation since Biederman does not specifically state a film layer, but a single surface film layer would be obvious to a toilet bar. Secondly, the surface of a toilet bar is a film and in inherently a single layer, and Biederman does not describe the toilet bar to have multiple layers. It is also note that the rejected claims 46, 49, 50 and 55-69 do not recite the thickness of the film and the claim that recited the thickness of the film has not been rejected over Biederman here. Further, while the toilet bar dissolves on wetted skin, it is noted that dissolution of the claimed film on a wetted skin tissue of mucosal epithelial tissue is the properties of the film, and that property is inherent to a composition that contains polyvinylpyrrolidone and polyethylene glycol as claimed in

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amended claim 46. Biederman does not have to specifically state a recognition of cleansing ability of the toilet bar because, a) cleansing in “cleansing composition” is the intended use of the composition and the prior art composition is capable of performing that function of intended use, and b) it is well known that toilet bar has cleansing use/properties. The recitation of the amended claim 46 saying “consisting essentially of” does not distinguish over the toilet bar of Biederman because, a toilet bar does not have multiple surfaces/film and Biederman does not teach a toilet bar having multiple surfaces/films. Regarding applicant’s reference as to the record not showing thin film composition or device according to claim 46 for use in commerce, it is noted that “for use in commerce” is the intended use of the composition and further, toilet bar inherently has a surface and it is well known that toilet bars are commercially available and are sold and bought on the market. Applicant has not provided factual showing that the toilet bar of Biederman is not/cannot have single film layer. “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

11. Claims 46 and 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Belsole (US 4,696,821).

Belsole is discussed above as teaching film composition that comprises nitroglycerin, polyvinylpyrrolidone, polyethylene glycol (abstract; column 2, line 9 to column 3 and line 22; Examples 1-4) and solvent (column 2, line 16) and meeting claim 46. Belsole is silent on the thickness of the film. But it would be obvious to one of ordinary skill in the art at the time of

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the invention to use a transdermal film having a desired thickness for application to the skin tissue to achieve the desired drug delivery.

12. Claims 46, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belsole (US 4,696,821) in view of Yukimatsu et al. (US 4,740,365).

Belsole is discussed above as teaching film composition that comprises nitroglycerin, polyvinylpyrrolidone, polyethylene glycol (abstract; column 2, line 9 to column 3 and line 22; Examples 1-4) and solvent (column 2, line 16) and meeting claim 46. Belsole does not teach the percent amount of the polyvinylpyrrolidone recited in claims 47 and 48. However, it is known in the art to use polyethylene glycol and polyvinylpyrrolidone at percent amounts of 20-80% in carrier composition for nitroglycerin or nifedipine or isosorbide dinitrate (column 4, lines 56; column 6, lines 9-11, 58, 59). Therefore, the ordinary skilled artisan, would have been able to use a combination of polyethylene glycol and 20-80% polyvinylpyrrolidone as the carrier composition for nitroglycerine according to the teaching of Yukimatsu.

13. Claims 46 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belsole (US 4,696,821) in view of Guittard et al. (US 4,576,604).

Belsole is discussed above as teaching film composition that comprises nitroglycerin, polyvinylpyrrolidone, polyethylene glycol (abstract; column 2, line 9 to column 3 and line 22; Examples 1-4) and solvent (column 2, line 16) and meeting claim 46. Belsole does not teach using PEG 4000 in the composition containing nitroglycerine. However, it is known in the art that PEG 4000 can be used with nitroglycerine according to Guittard (column 15, line 20;

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Examples 6, 7 and 9). Therefore, the ordinary skilled artisan, would have been motivated to use a combination of polyethylene glycol 4000 and polyvinylpyrrolidone as the carrier composition for nitroglycerine according to the teaching of Guittard.

No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

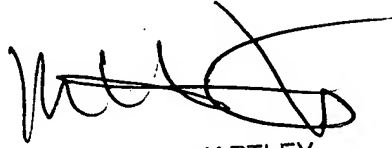
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER